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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,956	07/11/2000	ROBERT ANDREW BADLEY	IMIN.P-019	6821

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/22/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,956

Applicant(s)

BADLEY ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Preliminary Amendment Entry

1. Applicant's amendment and response filed 5/8/02 in Paper No. 16 is acknowledged and has been entered. Claims 1 and 12 have been amended. Currently, claims 1-3, 5-16, and 22 are pending and are under examination.

Rejections Withdrawn

2. In light of Applicant's argument, the rejection of claims 1-3, 5-16, and 22 under 35 U.S.C. 103(a) as being unpatentable over Garland et al. (WO 92/18867) in view of Tom-Moy et I. (EP 0 416 730), is hereby, withdrawn.
3. In light of Applicant's argument, the rejection of claims 5-6, 11-12 and 22 under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (WO 91/05262) in view of Tom-Moy et I. (EP 0 416 730), is hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 7, line 3 lacks antecedent support in reciting, "the intervening moiety".

Claim 12 remains unclear in reciting "properties". The term "properties" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "properties"), thereby rendering the scope of the claim unascertainable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 7-10, and 13-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (WO 91/05262) for reason of record.

Schramm et al. disclose a method of detecting the presence of an analyte in a sample comprising providing a first surface having a displaceable moiety reversibly immobilized, exposing the first surface to a sample wherein any analyte in the sample displaces the displaceable moiety, and detecting a signal. Schramm et al. teach contacting a first surface, upon which a displaceable moiety such as an antibody or analyte has been reversibly bound, with a sample wherein analyte in the sample displaces the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a specific antibody is bound and detecting the signal which can be produced by fluorescence or enzyme labels. Schramm et al. also teach that the two

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surfaces can be on separate or same supports and that planar, porous, or particulate surfaces may be used (see Abstract and pages 3-5 and 8).

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 7-8, 11-12, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Partin et al. (US 5,082,630).

Partin et al. disclose a fiber optic detector for use in immune testing. In practice, Partin et al. disclose coating a distal end of an optical fiber or waveguide (first surface) with antibody, then saturating the fiber with fluorescent-tagged drug derivative, i.e. antigen (displaceable moiety). Thereafter, the fiber is exposed to an airborne sample of the analyte, i.e. drug, to be detected. If the analyte is present, the analyte molecules displace some of the bound, fluorescent-tagged derivative, resulting in a decrease (modulation) in signal as detected by a detecting diode. The extent of the decrease is proportional to the concentration of drug molecules in the surrounding environment. See column 4, lines 49-64 and column 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5-6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (WO 91/05262) or Partin et al. (US 5,082,630).

Schramm et al. and Partin et al. have been discussed supra. Schramm et al. and Partin et al. differ from the instant invention in failing to disclose specifically using fusion protein in claim 5 or a mimitope in claim 6 as a displaceable moiety or in claim 22 as an intervening moiety.

The displaceable moiety and/or intervening moiety in the claimed invention appear to only have affinity requirements in their involvement in analyte detection, i.e. affinity of the displaceable moiety for the first surface lower than its affinity for the

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analyte, affinity of the intervening moiety for the analyte greater than its affinity for the displaceable moiety. Therefore, it appears that any binding member, including a fusion protein or a mimotope, that is capable of binding to a complementary partner, having affinity properties as aforementioned, would only constitute obvious variations of biological binding members taught by Schramm and/or Partin and which are known to routinely vary in the art depending on the purpose of use. Although silent in teaching use of "a fusion protein" or "a mimotope" for application in their methods, Schramm and Partin appear to be generic with respect to the types of specific binding members for use and application in their assay.

Response to Arguments

8. Applicant's arguments filed 4/30/01 have been fully considered but they are not persuasive.

a) Applicant argues that the rejected claims plainly exclude the teaching of Schramm et al., specifically, the detection step of Schramm et al.

In response, rejected claim 1 recites, "detecting the signal, ... performed by means other than surface plasmon resonance (SPR), ... the detectable signal is not generated unless and until the displaceable moiety is captured on the second surface whereupon the detection signal ... is generated. Schramm et al. at pages 11-12 of the disclosure states that upon being bound to the second surface, the displaced moiety converts the substrate into a colored product (in an enzyme assay), thus a colored signal is generated. Further, Schramm's detection method does not utilize SPR. It,

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therefore, appears that the method of Schramm et al. reads on the claimed invention as currently recited. Accordingly, the rejection of claims 1-3, 7-10, and 13-16 as being anticipated by Schramm et al. is maintained.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

9. Applicant's arguments with respect to 35 USC 103 rejections of the claims as being obvious over Schramm et al. or Garland et al. in view of Tom-Moy et al. have been considered but are moot in view of the new grounds of rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel

July 18, 2002 *gg*

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641